UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,010	02/27/2006	Cynthia C. Bamdad	13150-70089US	8164

7590 12/15/2009

JHK Law
P O Box 1078
La Canada, CA 91012-1078

EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,010	BAMDAD, CYNTHIA C.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,13,14,17,27 and 57-62* is/are pending in the application.

4a) Of the above claim(s) *27 and 57-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,13,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/09 has been entered.

2. Claims 1, 5, 13, 14, 17, 27 and 57-62 are all the pending claims for this application.

3. Claims 4 and 6 were cancelled and Claims 1 and 5 were amended in the Response of 11/10/09.

4. Claims 27 and 57-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

5. Claims 1, 5, 13, 14 and 17 are all the pending claims under examination.

6. This Office Action contains new grounds for rejection.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, first paragraph

Written Description

7. The rejection of Claims 5 and 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

The rejection is moot for cancelled Claim 6 and the rejection of Claim 5 is withdrawn in view of the amendment of the claims in the Response of 11/10/09 to delete the limitations for antibodies produced against:

the sequence of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions; ***or***

the functional variant of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions; ***or***

the fragment of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions.

Claim Rejections - 35 USC § 102

8. The rejection of Claims 1, 4-6, 13, and 14 under 35 U.S.C. 102(e) as being anticipated by Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of 1/31/08) is withdrawn.

Applicants allegations on p. 6 of the Response of 11/10/09 have been considered and are found persuasive in part and further in view of the claim amendments.

a) Applicants allege Kufe fails to understand the vast activity difference in effect between monovalent and bivalent MGFR specific antibody. Kufe fails to disclose the actual making of a monovalent antibody nor the motivation to create such a mono-valent antibody. Therefore, Kufe fails to provide an enabling disclosure of a mono-valent antibody.

Response to Arguments

The examiner respectfully submits Kufe discloses the single chain Fv or scFv antibody fragments at p. 14, lines 17-21. A single chain Fv is a "monovalent antibody" and is therefore taught by Kufe.

b) Applicants allege Kufe discloses that all antibodies against MUC 1/ECD region, regardless of whether they are bivalent or monovalent would act as stimulators of cell growth. Kufe fails to provide any distinctive effects between a bivalent antibody and the growth inhibiting effects of the monovalent antibody. Kufe simply fails to appreciate the effects of the monovalent antibody.

Response to Arguments

The examiner agrees that Kufe does not teach, suggest or appreciate a monovalent antibody against PSMGFR having the property of inhibiting proliferation of MUC1 expressing cells as in the amended claim set.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate ade in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The rejection of Claims 1, 5, 13, 14 and 17 under 35 U.S.C. 102(e) as being anticipated by Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

The rejection was maintained in the Office Action of 10/31/08 as follows:

"Applicants' allegations on p. 8 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "The present application claims the benefit of priority to PCT/US2005/032821 (See the Declaration), which in turn claims priority to U.S. Application No. 09/996,069, which is the application number for the cited Bamdad '199 patent application publication. Therefore, Bamdad '199 is not citable against the present application."

Response to Arguments

The current filed Oath/ Declaration (2/27/06) does not list any of the above alleged priority information; the application transmittal letter of 2/27/06 does not list any of the above alleged priority information; the cross-reference to related applications in the original filed specification (2/27/06) does not list any of the above alleged priority information; and the filing receipt of 7/27/07 does not list any of the above alleged priority information. Still further, the sequence listing does not list any of the above alleged priority information. No where in the file history is there documentation for the alleged priority claim. The rejection is maintained."

Applicants allegations on p. 5 of the Response of 11/10/09 have been considered and are not found persuasive. Applicants allege the present application is a 371 application of PCT/US2005/032821, which in turn claims priority to U.S. Application No. 09/996,069, which is the application number for the cited Bamdad '199 patent application publication. The first page of the PCT/US2005/032821 (WO2005/019269) publication is attached for the Examiner's review. Therefore, Bamdad '199 is not citable against the present application.

Response to Arguments

Applicants' comments are confusing.

First, no where on the attached first page of WO 2005/019269 does it mention "PCT/US2005/032821". Applicants make the statement on the record that the instant application is a 371 for a PCT application that is wholly unrelated to the instant invention. "PCT/US2005/032821" is an invention entitled "PROTEIN CONCENTRATE AND AN AQUEOUS STREAM CONTAINING WATER-SOLUBLE CARBOHYDRATES". The PCT No. for the instant 371 application is "PCT/US2004/027954."

Second, inasmuch as the cover page for WO 2005/019269 ("PCT/US2004/027954") shows international "PCT/US2004/027954" claims priority to U.S. provisional 60/498,260 (filed 8/26/03) *and* is a CON or CIP of 09/996,069 (filed 11/27/02), Applicants have not carried the complete priority claim into the national stage-entry for the instant 371 application.

The published international application claims priority to the provisional application 60/498,260 and the priority claim is properly indicated in the 1st sentence of the 371 SPEC.

The only reference to 09/996,069 is in the supplemental box of the Request of PCT/US04/027954, which indicates that the international application is a continuation-in-part of 09/996,069. The international application cannot claim priority to any application filed more than a year before the international filing date. The '069 application was filed more than one year before the international filing date for PCT/US04/027954.

IF applicant wishes to claim priority to the '069 application, they need that reference in the international application, but they must also make a priority claim in the national stage application in either the first sentence of the specification, or on an application data sheet. There does not appear to be an ADS in the application, and there is no claim to priority to the '069 application in the first sentence of the 371 SPEC. Therefore, in this national stage application, there is no claim to priority to the '069 application. That means that the only priority date is to the provisional, filed in 2003, which would be the date for the purpose of prior art.

This application is the national stage of PCT/US04/27954, and while the publication of this application indicates that the international application is related to 09/996,069, it does not claim priority to it, and if Applicants want a priority claim in a national stage application, they must make the claim in that national stage application either in the 1st sentence of the SPEC or in an ADS.

The rejection is maintained.

10. The rejection of Claims 1, 5, 13, and 14 under 35 U.S.C. 102(e) as being anticipated by Wreschner et al. (US 20050019324; published 1/27/05; filed 3/26/02; cited in the PTO 892 form of 1/31/08) is maintained.

The rejection was maintained in the Office Action of 10/31/08 as follows:

"Applicants' allegations on p. 9 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Wreschner discloses a monoclonal antibody (BOS7D10) against MUC1 that inhibits cell growth. However, the disclosed antibody appears to be a bi-valent antibody. Since Wreschner is silent as to the anti-cell proliferation effects of the monovalent antibody over bivalent antibody, the presently claimed monovalent antibody is distinguished over the bivalent antibody described in Wreschner."

Response to Arguments

Wreschner discloses an isolated antibody or fragment including monovalent and bivalent antibodies and fragments [0034; 0047], which specifically binds to an epitope in the extracellular region of an isoform of MUC1 protein [0019] where the epitope is located in the 15 amino acid sequence that resides at the N-terminal portion of the 59 amino acid segment which is located directly N-terminal to the transmembrane domain of the MUC1/Y, MUC1/X and MUC1/REP proteins [0044], a pharmaceutical composition comprising the antibody [0056]. Because the claims broadly recite any antibody binding to any region within an MGFR domain of a MUC1 protein inclusive of the PSMGFR domain and the specification defines these domains as extracellular domains, and Kufe teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, which corresponds to the peptide sequence for the extracellular domain of Muc-1 described in Wreschner, the claims are considered to encompass an antibody binding to an unmodified sequence for the extracellular (SEQ ID NO:36 (native PSMGFR)), where zero modifications are read into the range.

Wreschner's disclosure for making monoclonal antibodies is explicit. Wreschner's disclosure for making monovalent antibodies is explicit. Applicants' argument that Wreschner does not appreciate the difference(s) between monovalent and bivalent antibodies is irrelevant and gratuitous because none of the instant claims are drawn to a bivalent antibody. The rejection is maintained."

Applicants' allegations on pp. 6-7 of the Response of 11/10/09 have been considered but are not found persuasive. Applicants allege Wreschner '324 discloses that its antibody was preferably made against the sequence located in the 15 amino

acid sequence that resides at the N-terminal portion of the 59 amino acid segment. This 15 amino acid sequence includes SVVVQLTLAFREGTI. However, only the final "GTI" overlaps with the PSMGFR sequence of the claimed invention. Accordingly, it is believed that the Wreschner '324 antibody lies outside the scope of the antibody of the claimed invention.

Response to Arguments

The examiner respectfully submits that Applicants have not established by a preponderance of the evidence that the epitope for the monovalent antibody of Wreschner would not comprise or be overlapping with the final "GTI" residues of the PSMGFR sequence. Also Wreschner teaches examples of monoclonal antibodies binding within this region and having the property of growth inhibition of MCF7 breast cancer cells.

The claimed antibody appears to be the same as the prior art antibodies, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). The rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The rejection of Claims 1 and 17 under 35 U.S.C. 103(a) as being unpatentable over Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of of 1/31/08) in view of Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

The rejection was maintained in the Office Action of 10/31/08 as follows:

> "Applicants' allegations on p. 9 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Since Bamdad '199 is a priority application and therefore cannot be cited against the present application, this rejection is fails to be applicable to the present application."
> Response to Arguments
> See the examiner's comments under section 12 above as they apply here to the Bamdad reference. The rejection is maintained."

Applicants' allegations on pp. 7-8 of the Response of 11/10/09 have been considered but are not found persuasive. Applicants allege the amended Claim 1 includes the limitations for cancelled Claim 4.

Response to Arguments

The examiner submits Kufe discloses the single chain Fv or scFv antibody fragments at p. 14, lines 17-21. A single chain Fv is a "monovalent antibody" and is therefore taught by Kufe.

Bamdad teach bivalent and monovalent antibodies [0099; 0122; 0230] that bind to PSMGFR [0062] or fragments thereof [0277-278] of MUC1, and compositions

comprising pharmaceutical compositions, and kits comprising the antibody [0011; 0143]. Finally, Bamdad teaches "When tumor cell lines, in which the MUC1 receptor is homogeneously expressed across the entire cell surface, are treated with an IgG antibody raised against the MGFR portion of the MUC1 receptor, the rate of cell proliferation is greatly enhanced, see FIG. 5. Since IgG antibodies are bivalent, i.e. one antibody simultaneously binds to two adjacent MGFR portions on the cell surface, these results demonstrate that the antibody acts as an activating ligand, mimicking the effect of a growth factor, which dimerizes MGFR portions, and thus triggers a cell proliferation signaling cascade which is consistent with signaling via the cytoplasmic tails of the receptors. This finding leads to two conclusions. First, an activating ligand(s) that binds to the MGFR portion of the MUC1 receptor causes inductive multimerization of the receptor. Secondly, an effective therapeutic strategy is therefore to block the MGFR portion of the receptor with a monomeric composition, thus preventing inductive multimerization and subsequent signaling cascades. For example, *a single chain, or monovalent, antibody raised against the MGFR portion of the MUC1 receptor would function as an effective anti-cancer therapeutic*" [0099]. Bamdad provides more than sufficient motivation to produce a monomeric form of an antibody to the PSMGFR domain in order to reduce cell proliferation of MUC1-expressing cells vis-a-vis decreased dimerization of the surface antigen

The rejection is maintained.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 1, 5, 13, 14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claims 1, 5, 13, 14 and 17 recite the broad recitation "An isolated monovalent antibody or antigen-binding fragment thereof that specifically binds to MUC1 Growth Factor Receptor (MGFR)", and the claim also recites "the antibody or antigen-binding fragment thereof specifically

binds to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR)," which is the narrower statement of the range/limitation.

b) Claim 5 is indefinite for the recitation "An isolated antibody or antigen binding fragment" which is considered to be a broadening limitation for the species of antibody than what is claimed in Claim 1, namely, a monovalent antibody. Amending the claim to recite "An isolated monovalent antibody or antigen binding fragment" could overcome the rejection.

c) Claims 5, 13, 14 and 17 recite the limitation "antibody or antigen binding fragment thereof". There is insufficient antecedent basis for this limitation in the claims and it is not clear if the "antibody" is referring to "an isolated monovalent antibody or antigen-binding fragment thereof that specifically binds to MUC1 Growth Factor Receptor (MGFR)", *or* "the antibody or antigen-binding fragment thereof specifically binds to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR)".

Clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

13. Claims 1, 5, 13, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 5, 13, 14 and 17 are interpreted as being drawn to the genus of monovalent antibodies having the combined properties of a) binding to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells. It is the examiner's position that the specification and the prior art do not support the genus of monovalent antibodies meeting the structure/function requirements for the instant scope of the claims.

Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001) revised training materials 3/25/08), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses the making monovalent fragments from polyclonal antibodies against the GTINVHDVETQFNQYKTEA ASPYNLTISDVSVSDVPFPFSAQSGA peptide (var-PSMGFR; SEQ ID NO:7) (Example 8) using papain digestion (Example 9); and comparing the bi- and monovalent forms of the antibodies on cell proliferation using the tumor cell lines 1500, 1504 and BT474 (Example 11). The specification does not support a monovalent antibody that binds to both to MUC1 Growth Factor Receptor (MGFR)" and Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR) as well as inhibiting proliferation of just *any* MUC1 expressing cells.

b) Disclosure of drawings or structural chemical formulas: the specification and

drawings do not show that applicant was in possession of the genus of monovalent antibodies having the combined properties of a) binding to to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or iv) functional characteristics coupled with correlation between structure and function for the genus of monovalent antibodies having the combined properties of a) binding to to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells.

d) Method of making the claimed invention: the specification teaches screening for antibodies and making monovalent forms that bind MGFR or PSMGFR. The specification teaches screening for cell proliferation with the antibodies.

e) Level of skill and knowledge in the art: the screening antibodies and identifying regions within proteins to which they bind was well established at the time of the invention.

f) Predictability in the Art: the art does not appear to teach the genus of monovalent antibodies having the combined properties of a) binding to to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells.

Applicants have not demonstrated with sufficient evidence the genus of

monovalent antibodies having the combined properties of a) binding to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells. The ordinary artisan could reasonably conclude that Applicants were not in possession of the claimed genus of antibodies at the time of application filing.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Primary Examiner, Art Unit 1643